



Original 510(k)
Fixture Mount Kit

NOV - 5 1996

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K96321

Section 7

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.
Address: 22895 Eastpark Drive
Yorba Linda, CA 92887
U.S.A.
Contact's Name: Paul Gasser
Regulatory Affairs Specialist
Phone: 714-282-4800
Date Prepared: August 1996

Device Names:

Common Name: Kit
Trade Name: Fixture Mount Kit
Classification Name: Surgical Kit - General

Predicate Device:

Substantial equivalence is claimed to Nobelpharma's Instrument set for fixture installation, SDIB 101.

Device Description:

How device functions: The Steri-Oss kit is designed to assist in fixture placement.

Device Description (cont.):

Scientific concepts: Does not apply.

Characteristics: The tray is composed of titanium and the instruments are composed of titanium or steel.

Intended Use:

The kit is indicated for use to assist in fixture placement.

Comparison to Predicate:

The following table provides a comparison of the technological characteristic of the Steri-Oss kit to the predicate.

Item	Predicate	Steri-Oss
Material	Titanium	Titanium
	Steel	Steel
	Aluminum	Silicone
Sterility	Non-Sterile	Same

Performance Data:

Not applicable.